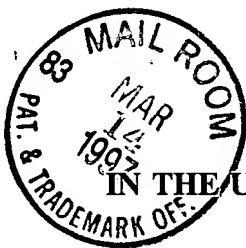


111-109100
#38 DAYC for Ethyl



Patent
Attorney's Docket No. 000445-016

In re Patent of)
Lester, P.J. Burton)
U.S. Patent No.: 4,912,155) Attn: Box Patent Extension
Issued: March 27, 1990)
For: ANTIOXIDANT AROMATIC)
FLUOROPHOSPHITES)

240 DD 05/19/97 4912155
1 111 1,091.00 CK

APPLICATION FOR EXTENSION OF PATENT TERM

Assistant Commissioner of Patents
Washington, D.C. 20231

Sir:

RECEIVED
MAY 16 1997
PATENT EXTENSION
AC PATENTS

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This application is submitted by including an original, a certified copy and three working copies.

Under the provisions of 35 U.S.C. §156 and in accordance with 37 C.F.R. §1.710 *et. seq.*, the owner of record of U.S. Patent No. 4,912,155 ("the '155 Patent"), requests that the term of the '155 Patent be extended 1390 days to expire on January 15, 2011. The '155 Patent issued March 27, 1990, and would in view of GATT, and in the absence of an extended term, expire on March 27, 2007. The named inventor is Lester P.J. Burton. The patent is assigned of record to Ethyl Corporation, which was reorganized to form Albemarle Corporation, an independent corporation. While the application was originally filed by Ethyl Corporation, the FDA had been informed that Albemarle

Corporation was the petitioner of record for this food additive petition pursuant to the reorganization.

The items required by 37 C.F.R. §1.740(a) follow in §§ I-XVII.

I. APPROVED PRODUCT

The approved product is 2,2'-ethylidenebis(4,6-di-tert-butylphenyl)fluorophosphonite, which was approved for use as an antioxidant in adhesives and in the preparation of polymers intended for contact with food, as set forth in 62 FR 2011 published on January 15, 1997.

II. APPLICABLE FEDERAL STATUTE

The approved product, 2,2'-ethylidenebis(4,6-di-tert-butylphenyl)fluorophosphonite, was subject to regulatory review under Section 409 of the Federal Food, Drug and Cosmetic Act ("the Act") (21 U.S.C. §348).

III. PRODUCT APPROVAL DATE

The approved product, 2,2'-ethylidenebis(4,6-di-tert-butylphenyl)fluorophosphonite, received permission for commercial marketing or use under Section 409 of the Act on January 15, 1997.

IV. APPLICATION FILING DEADLINE

The present application is being submitted within the sixty-day period permitted for submission pursuant to 37 C.F.R. §1.172(f). The last day on which the application can be submitted is March 16, 1997.

V. PATENT FOR WHICH EXTENSION IS SOUGHT

The patent for which an extension is being sought is U.S. Patent No. 4,912,155, which issued on March 27, 1990, in the name of Lester P.J. Burton. The patent is assigned of record to Ethyl Corporation, now Albemarle Corporation pursuant to reorganization. Since this patent issued before June 8, 1995, the effective date of the Uruguay Round Agreements Act it is entitled to a patent term of the longer of twenty (20) years from the application filing date or seventeen (17) years from the patent issue date. For the '155 Patent, a patent term of seventeen (17) years from the issue date of March 27, 1990 is longer. The patent would thus expire on March 27, 2007.

A reissue application relating to this patent was filed on June 13, 1991, and has been assigned reissue Serial Number 07/714,441.

VI. COPY OF PATENT

A copy of U.S. Patent No. 4,912,155 is enclosed herewith as Appendix A, including the entire specification and claims.

VII. COPY OF CERTIFICATE OF CORRECTION, DISCLAIMERS, MAINTENANCE
FEE PAYMENT RECEIPTS OR REEXAMINATION CERTIFICATES

There is no certificate of correction, disclaimer or reexamination certificate for this patent. A copy of a maintenance fee payment receipt is enclosed in Appendix B.

VIII. SHOWING THAT PATENT CLAIMS APPROVED PRODUCT

U.S. Patent No. 4,912,155 claims the approved 2,2'-ethylidenebis(4,6-di-tert-butylphenyl)fluorophosphonite compound, and compositions comprising the same.

The following patent claims read directly on the approved product:

Product Claims

Claim 1 reads on the approved product. Claim 1 recites as follows:

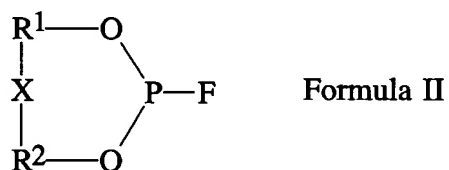
1. An aromatic fluorophosphorus compound suitable for use as an antioxidant said compound being selected from fluorophosphorus compounds having the structure:



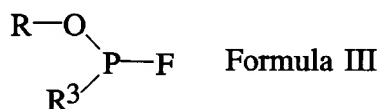
wherein R is an substituted aryl group wherein the substituents are tert-alkyl groups:



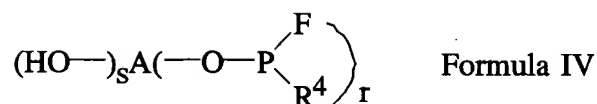
wherein R' is a substituted aryl group wherein the substituents are selected from sec-alkyl, tert-alkyl, aralkyl, cycloalkyl, hydroxy, alkoxy, aryloxy, halo, acyloxy, and alkoxy carbonylalkyl:



wherein R¹ and R² are substituted or unsubstituted aryl groups wherein the substituent are selected from alkyl, aryl, aralkyl, cycloalkyl, hydroxy, alkoxy, aryloxy, and halo; and X is selected from the group consisting of a single bond connecting R¹ and R² and divalent bridging groups selected from divalent aliphatic hydrocarbon groups containing 1-12 carbon atoms, —O— and —S_q— wherein q is an integer from 1 to 3;



wherein R is a substituted or unsubstituted aryl group wherein the substituents are selected from alkyl, aryl, aralkyl, cycloalkyl, hydroxy, alkoxy, aryloxy, halo, alkoxycarbonyl, alkoxycarbonylalkyl and acyloxy, and R³ is selected from the group consisting of alkyl, cycloalkyl, aralkyl, aryl, substituted aryl, alkoxy, cycloalkoxy and aralkoxy; and



wherein A is a mono- or poly-nuclear aromatic group, R^4 is independently selected from fluorine, aryloxy, alkylaryloxy, alkoxy and polyalkoxy, r is an integer from 1 to 4, s is an integer from 0 to 3 and (r+s) equals the valence of A. Because 2,2'-ethylenedibis(4,6-di-tert-butylphenyl)fluorophosphonite is a compound encompassed by the formula of claim 1, more specifically, a compound of Formula II, claim 1 reads on the approved product.

Claim 5 also reads on the approved product because it specifically recites a "compound of claim 1 namely: 2,2'-ethylenedibis(4,6-di-tert-butylphenyl)fluorophosphonite."

Claim 8 recites:

8. Organic material normally susceptible to gradual oxidative degradation when in contact with oxygen, said organic material containing an antioxidant amount of an aromatic fluorophosphorus compound, said compound being characterized by having at least one benzene group bonded through oxygen to a trivalent phosphorus atom and at least one fluorine atom bonded to said phosphorus atom.

Claim 9 depends from claim 8 and specifies that the fluorophosphorus compound is selected from the group of compounds having the structure of Formula I, Formula II, Formula III and Formula IV, as set forth above in claim 1.

The approved product also reads on claims 10 and 11, which recite the compositions of claims 8 and 9, respectively, wherein the organic material is a polymer of an olefinically unsaturated monomer.

The approved product further reads on dependent claims 19-21. Claim 19 depends from claim 9 and specifies that the fluorophosphite compound has Formula II. Claim 20 depends from claim 19 and recites that the "substituent groups are alkyls containing 1-20 carbon atoms," and claim 21 depends from claim 20 and specifies that the fluorophosphorus compound is 2,2'-ethylidenebis(4,6-di-tert-butylphenyl)fluorophosphonite. These claims read on the approved product because 2,2'-ethylidenebis(4,6-di-tert-butylphenyl)fluorophosphonite is the approved product

Claims 32, 33, 38, 39 and 41 recite that the organic compositions of claims 8, 9, 19, 21, 39 and 25, respectively, contain about 0.005-5 wt. percent of a phenolic antioxidant. The approved product also reads on these claims because the claimed organic compositions comprise the approved 2,2'-ethylidenebis(4,6-di-tert-butylphenyl)fluorophosphonite compound.

IX. INFORMATION PURSUANT TO 35 U.S.C. §156(g)

The information required by 37 C.F.R. §1.740(a)(10)(iv) is set forth below:

Rat oral and dermal LD₅₀ toxicity tests were initiated on July 21, 1986.

Food Additive Petition (FAP) 1B4281 was submitted to the FDA on August 1, 1991.

Food Additive Petition (FAP) 1B4281 was granted by the FDA on January 15, 1997.

Further, the above identified patent is eligible for an extension of patent term, since the following requirements of §156(g) are met:

- (1) the above identified patent has not expired prior to the filing of this application for extension of patent term;
- (2) the term of the patent has never been extended;
- (3) the application for extension of patent term is being submitted by the patent attorney or agent for the owner of record of the above-identified U.S. Patent No. 4,912,155 for which a patent term extension is sought, authorized to practice before the U.S. Patent and Trademark Office, who has general authority from said owner to act on behalf of said owner in patent matters including the execution of the APPLICATION FOR EXTENSION OF PATENT TERM being submitted pursuant to 37 C.F.R. §1.740;
- (4) the product has been subject to a regulatory review period before its commercial marketing or use in the United States;

(5) the permission for the commercial marketing or use of the product after such regulatory review period is the first such permitted commercial marketing or use of the product under the provision of law under which such regulatory review period occurred.

X. ACTIVITIES DURING REGULATORY REVIEW PERIOD

Significant activities undertaken by the marketing applicant during the applicable regulatory review period with respect to the approved product and the dates applicable to such activities are as follows:

Toxicity Tests

Test Article Preparation Date	Test Date	Tests Performed on that Lot
7/21/86	Oct/Dec. 1986 Nov. 1986 Nov. 1986 Dec. 1986 1986	Rat Oral and Dermal LD50 Ames Mutagenicity Rat Hepatocyte DNA Repair Eye and Skin Irritation Herbicide/Fungicide/Insecticide Potential
12/16/87	1987	Solubilities (Water, corn oil, acetone, THF)
1/25/88	1988-1990 Nov. 1989 June 1988 June 1988 1988 June 1988 1988 July, 1988 1988	2 year Chemical Stability Study Chicken Preliminary Toxicity Studies Rat, 28 day repeated dose Oral Study Rabbit Dermal LD50 (OECD) Biodegradation (OECD) Eye and Skin Irritation (OECD) Trout and Daphnia Toxicity Guineal Pig Hypersensitivity 14 day stability (corn oil); solubilities
7/9/88	1988 1988	Biodegradation Bioaccumulation
12/2/88	Nov. 1989 1989	Chicken Neurotoxicity Dog - Preliminary Range Finding Studies

1/9/89	Oct. 1990	Dog, 90 day study
	Oct. 1990	Rat, 90 day in utero study
1/9/89	1989	Rat, Preliminary Studies
	1990	Ames Mutagenicity
	1990	Mammalian Cell Forward Mutation Study

Further activities undertaken by the marketing applicant during the regulatory review period are as follows:

<u>Date</u>	<u>Person or Entity</u>	<u>Action</u>
August 27, 1987	EPA/Ethyl	Premanufacturing Notice as required under the Toxic Substances Control Act filed with EPA; Negotiations on Consent Order
May 12, 1988		90 day on Premanufacturing Notice as required under the Toxic Substances Control Act
November 14, 1988		First commercial material
April 14, 1989	D. Dixler Keller and Heckman	N. O'Malley sends toxicity test protocols to Keller and Heckman for review; dosage questions
September, 1990		First Market Development Unit campaign
October, 1990		Toxicity Final Reports received by Ethyl
May 14, 1991	Hazleton Laboratories	Migration Studies Report
July 15, 1991	Keller and Heckman, Ethyl, FDA	Pre-submission conference with FDA; FDA asks for competitive antioxidants, validation of the X-ray fluorescence spectroscopy method, reference articles on methodology

August 1, 1991	Keller and Heckamn John B. Dubeck	Petition submitted by Keller and Heckman to FDA
August 16, 1991	FDA	FDA indicates petition accepted for filing
October 29, 1991	FDA	Question on an item in environmental section
December 6, 1991	Ethyl	Response to environmental question submitted
January 6, 1992	Dan Harrison Consumer Safety Officer, FDA	Acknowledges receipt of response, indicates it is "substantive amendment" and sets 1/6/92 as new filing date
April 8, 1992	Keller and Heckman	Keller and Heckman told by FDA scientific review extended by 90 days
June 18, 1992	Dan Harrison	Environmental review complete, "no significant impact"
July 17, 1992	Dan Harrison	Keller and Heckman told chemistry review well underway, but reviewer expected to have "minor" questions
July 29, 1992	Dan Harrison	Chemistry review complete, but additional data needed (Analytical procedures and results)
July 29, 1992	John B. Dubeck	FDA requests more chemistry information
August 18, 1992	Dan Harrison FDA	John B. Dubeck sends response to chemistry questions

August 19, 1992	FDA	Response identified as being "substantive amendment", new filing date, 90 day extension
November 5, 1992	Dan Harrison	Told Keller and Heckman chemistry review would take another couple of months
February 4, 1993	Keller and Heckman	Dan Harrison says petition under review
April 7, 1993	Keller and Heckman	FDA indicates chemistry section completed. Dan Harrison indicates tox review would be completed in one month.
May 6, 1993	FDA	Dan Harrison indicates petition still under review but no predictions
June 2, 1993	Dan Harrison	Petition still under review. Keller and Heckman approached T.C. Brown of Additives Branch unofficially. Brown agrees petition has not been reviewed expeditiously and promises prompt attention
June 14, 1993	FDA	Keller and Heckman told that FDA has lost the rat toxicology report. Keller and Heckman delivers their copy promptly and admonishes FDA not to call this a substantive amendment.
August 4, 1993	John B. Dubeck	John B. Dubeck asks status of review
August 10, 1993	John B. Dubeck	Dan Harrison states toxicologist actively reviewing data

September 7, 1993	John B. Dubeck Keller and Heckman	FDA requests further toxicity information on the 90 day studies and a literature review on impurities
September 15, 1993	N. O'Malley	Discussions with Holly Foley. She had prepared petition and had been unaware of additional studies that had been conducted.
October 7, 1993	N. O'Malley/Robert L. Smith Holly Foley	Asked for meeting with FDA to discuss questions on tox studies
October 14, 1993	Dan Harrison, FDA	John B. Dubeck sends agenda for tox discussion meeting
October 18, 1993	N. O'Malley Ethyl	John B. Dubeck requests meeting for Nov. 1, meeting FDA's request for 2 week notification
November 9, 1993	Dan Harrison, FDA	John B. Dubeck confirms meeting on tox issues; to be held November 23
November 9, 1993	John B. Dubeck Keller and Heckman	N. O'Malley sends analytical data and toxicity info indicating other toxicity information
November 23, 1993	FDA, Ethyl Keller and Heckman	Meeting at FDA to discuss request for additional information FDA withdraws statistical questions, and pre and post test blood value questions. FDA requests any additional toxicity information.

January 25, 1994	Keller and Heckman	Receive tox response package from N. O'Malley
January 26, 1994	Dan Harrison Indirect Food Adds.	Receives tox response from Keller and Heckman
January 27, 1994		FDA officially receives response
January 31, 1994	John B. Dubeck Keller and Heckman	Receives letter from Dan Harrison, receipt of "amendment" on January 27. Under 171.6 establishes new filing date. Will review within 90 days or ask for additional 90 days.
February 4, 1994	N. O'Malley Ethyl	John B. Dubeck sends letter indicating that FDA had received package on 26th Notes that 90 days is <u>pro forma</u> for amendments
February 10, 1994	Robert L. Smith, N. O'Malley, with D. Harrison, FDA	Robert L. Smith expresses concern Conference call with language of FDA letter establishing new filing date. Dan Harrison indicates standard language and information would be reviewed as toxicologist's work scheduled allowed
April 28, 1994	John B. Dubeck to N. O'Malley	Dan Harrison contacted. States that review will be extended
April 29, 1994	Coleman to John B. Dubeck	FDA extends scientific review of petition for an additional 90 days. (Section 409(c)(2) of FDCA

May 11, 1994	Smith to Lowell Harmison	Contract with Lowell Harmison to expedite Petition review within FDA
May 11, 1994	Lowell Harmison to Smith	Application is stuck in toxicology review. Will ask that it be reassigned out of the branch to someone that can review it.
June 8, 1994	John B. Dubeck to N. O'Malley	Discussions with Dan Harrison May 31- FDA not legally required to act on petition until July 26. Two 90 day extensions after January additional information valid.
July 18, 1994	Lowell Harmison	FDA states petition moved from group of 21 to group of 10 under active review
July 19, 1994	Lowell Harmison	Letter from Albemarle to FDA noting petition has been filed over 3 years.
August 8, 1994	Lowell Harmison	Talks with Tom Brown. Application reassigned from "Karen" to Catherine Raffael. Tom Brown's last day with agency is Sept. 30, 1994
August 15, 1994	N. O'Malley, Springborn Laboratories	Quality Assurance at lab informs N. O'Malley that FDA investigator and 3 reviewers from DC were there for week long data audit on Dog and Rat studies (8/15-8/19) (C. Whiteside, J. J. Welsh, R. Chanderbahn; Division of Health Effects Evaluation)

August 19, 1994	Springborn Labs	Form 483 (FDA form used to record findings from an audit for Good Laboratory Practices compliance at a testing laboratory) issued to Springborn on findings not related to X398 study
October 13, 1994	Lowell Harmison	Active review of toxicologist; FDA Indicated that a chemistry review was triggered after additional tox studies were submitted earlier in '94
November 10, 1994	Dan Harrison to Lowell Harmison	Letter from FDA with more tox questions on 90 day rat, and new question on 28 day rat study (submitted suppl.)
November 30, 1994	Lowell Harmison to Smith	Active review going on will continue while questions being answered
December 8, 1994	N. O'Malley sends response to Lowell Harrison to hand historical info, carry to FDA	Response to FDA; and letters on 28 and 90 day rat studies
December 8, 1994	Lowell Harmison	Dan Harrison of FDA requests three copies of Charles River Historical Data that had been included as courtesy in response
January 17, 1995	Lowell Harmison to Smith	Toxicology is still being reviewed
February 7, 1995	Lowell Harmison to Smith	Dan Harrison stated that tox review didn't really get underway until July, 1994.

March 10, 1995	Coleman to Lowell Harmison	FDA to extend scientific review for 90 days effective March 12. No reason given.
May 7, 1995	Dan Harrison Ind. Food Add.	Lowell Harmison sent draft letter from Dan Harrison Duplicates questions from Nov. 1994
May 11, 1995	Lowell Harmison	Lowell Harmison sends letter pointing out error
May 12, 1995	Dan Harrison	Corrected letter from Harrison, 3 questions on dog study
May 18, 1995	N. O'Malley	Letter to FDA indicating we will respond and asking clarification on Question 3.
June 5, 1995	Kathleen C Raffaello FDA	Clarification of questions of 4/24/95
July 19, 1995		Robert L. Smith, Lowell Harmison to meet with Rulis
July 26, 1995		FDA acknowledges Albemarle response information; New filing date, 90 day extension
July 31, 1995		FDA asks for more information on mutagenicity tests
February 16, 1996	L.L. Wen/N. O'Malley	Note to Robert L. Smith; review of draft final rule differs only in few points from our proposed rule in 1991.

February 28, 1996	Robert L. Smith	Letter to Dan Harrison; review of the portions of the draft final rule sent to Lowell Harmison, no objections
May 30, 1996	Keller and Heckman	Draft petition submitted to FDA
August 8, 1996		Draft language received for petition
August 9, 1996		Albemarle accepts language in draft petition
January 15, 1997		Petition approved and published Fed. Reg. Vol 62, 20111 (copy enclosed in Appendix C)

INDEX OF NAMES

Keller and Heckman	Initial counsel on petition
D. Dixler	Attorney at Keller and Heckman Washington, D.C.
John B. Dubeck	Attorney at Keller and Heckman Washington, D.C.
Holly Foley	Attorney at Keller and Heckman Washington, D.C.
Robert L. Smith	Director, Toxicology, Regulatory and Environmental Affairs Albemarle Corporation (formerly Ethyl)
L.L. Wen	Senior Regulatory Advisor Toxicology, Regulatory and Environmental Affairs Albemarle Corporation
N. O'Malley	Toxicology Advisor Albemarle Corporation
Dan Harrison	FDA, Indirect Food Additives
Lowell Harmison	Consultant to Albemarle Corporation
Market Development	Production site at Baton Rouge, La. Unit
Quality Assurance	Internal Audit Unit at testing laboratory

XI. ELIGIBILITY OF PATENT FOR EXTENSION

In the opinion of Applicant, the above identified patent is eligible for an extension of the term for 1390 days, and to thus expire on January 15, 2011. The length of the claimed extension of 1390 days was determined by Applicant, pursuant to 37 C.F.R. §1.775, to be fourteen years from the date of the FDA final approval, as described below:

A. Length of the Regulatory Review Period (Rule 776(c))

1. *Period Pursuant to Paragraph (c)(1)*

The period defined at 37 C.F.R. §1.776(c)(1) began on July 21, 1986 (the date of the first major health effects test) and ended on August 1, 1991 (the date the food additive petition ("FAP") was filed). The (c)(1) period is thus 1837 days.

2. *Period Pursuant to Paragraph (c)(2)*

The period defined at 37 C.F.R. §1.776(c)(2) began August 1, 1991 (the date of submission of the FPA submitted pursuant to Section 5348 of the Act) and ended January 15, 1997 (the date of publication of approval in the Federal Register). The (c)(2) period is thus 1994 days.

The total (c)(1) and (c)(2) time period is thus 3831 days.

B. Term of the Patent as Extended (Rule 776(d))

The term of the patent as extended was then calculated to expire on April 14, 2013, pursuant to 37 C.F.R. §1.776(d).

1. *(d)(1) Period (Days Subtracted from Regulatory Review Period)*

The regulatory review period upon which the period of extension is based is calculated by subtracting from the regulatory review period as determined in (c)(1) and (c)(2) of this section the following:

- (i) *The number of days in the periods of paragraphs (c)(1) and (c)(2) above which were on or before March 27, 1990, the issue date of the original patent.*

The number of days in the periods of paragraphs (c)(1) and (c)(2) which were on or before March 27, 1990, the issue date of the patent, is 1345. The number of days to be subtracted from the regulatory review period is thus 2486.

- (ii) *The number of days in the periods of paragraphs (c)(1) and (c)(2) during which the Applicant did not act with due diligence.*

In Applicant's opinion, marketing applicant acted with due diligence as defined at 35 U.S.C. §156(d)(3) during the above-calculated periods of paragraphs (c)(1) and (c)(2). Accordingly, zero days are subtracted from the regulatory review period.

- (iii) *One-half the number of days remaining in the period defined by paragraph (c)(1) of this section after that period is reduced in accordance with paragraphs (d)(1)(i) and (ii) of this section (ignoring half days for purposes of subtraction).*

There are 1837 days in the period defined by paragraph (c)(1), which should be reduced by 1345 days. The number of days remaining in the period defined by paragraph (c)(1) is 492 days. One-half of 492 days, ignoring half days for purposes of subtraction, is 246. Subtracting 246 days from 2486 results in a time period of 2240.

Thus, the period determined according to paragraph (d)(1) is 2240 days.

2. *(d)(2) Date*

The number of days determined in paragraph (d)(1), 2240 days, added to the original term of the patent, i.e., 17 years from the original issue date, results in an extended patent expiration date of May 14, 2013.

3. *(d)(3) Date*

Fourteen years added to the January 15, 1997, date of approval under the Federal Food, Drug and Cosmetic Act, yields an extended patent expiration date of January 15, 2011.

4. *(d)(4) Date*

Comparing the extended terms determined according to paragraphs (d)(2) and (d)(3), the earlier date is January 15, 2011.

5. *(d)(5) Date*

The original patent issued after September 24, 1984. Five years added to the original expiration date of the patent is March 27, 2012.

By comparing the dates obtained pursuant to paragraphs (d)(4) and (d)(5)(i) of this section with each other, the earlier date is January 15, 2011.

6. *(d)(6) Date*

The original patent was issued after September 24, 1984. This section thus does not apply.

XII. ACKNOWLEDGMENT OF DUTY TO DISCLOSE

Applicant hereby acknowledges a duty to disclose to the Commissioner of Patents and Trademarks and the Secretary of Health and Human Services any information which is material to the determination of entitlement to the extension sought pursuant to 37 C.F.R. §1.765.

XIII. APPLICATION FEE

Applicant submits herewith a check for \$1090.00 in payment of the fee set forth at 37 C.F.R. §1.20(j).

The Commissioner is hereby authorized to charge any appropriate fees that may be required by this paper, and to credit any overpayment, to deposit Account No. 02-4800.

XIV. CORRESPONDENCE ADDRESS

Please direct all correspondence and inquiries regarding this matter to:

Teresa Stanek Rea
BURNS, DOANE, SWECKER & MATHIS, L.L.P.
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Alexandria, VA 22313-1404
Phone: (703) 836-6620
Fax: (703) 836-2021

XV. DUPLICATE OF APPLICATION AND CERTIFICATION

Applicant encloses herewith a copy of the present application papers, and certifies that said copy is a duplicate of the application papers. For the convenience of the Senior Legal Advisor of the Patent Office, Applicant is also enclosing three (3) additional copies of the application.

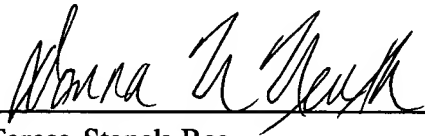
XVI. DECLARATION

A Declaration pursuant to 37 C.F.R. §1.740(b) is attached hereto.

In view of the foregoing, an extension of the term of the above identified patent is respectfully requested.

Respectfully submitted,

BURNS, DOANE, SWECKER & MATHIS, L.L.P.

By: 
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